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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/080,101	02/19/2002	Klaus Gregorius Nielsen	674542-2003	7906
20999	7590	11/24/2004	EXAMINER	
FROMMER LAWRENCE & HAUG 745 FIFTH AVENUE- 10TH FL. NEW YORK, NY 10151			NICHOLS, CHRISTOPHER J	
			ART UNIT	PAPER NUMBER
			1647	

DATE MAILED: 11/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/080,101

Applicant(s)

NIELSEN ET AL.

Examiner

Christopher J Nichols, Ph.D.

Art Unit

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 15 September 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,4-6 and 8-38 is/are pending in the application.
- 4a) Of the above claim(s) 26-38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,4-6,8-14 and 16-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1,4-6 and 8-38 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 February 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 9.6.02.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Status of Application, Amendments, and/or Claims***

1. The Response and Amendment filed 15 September 2004 has been received and entered in full.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Withdrawn Objections And/Or Rejections***

3. The Rejection of claims **1-25** under 35 U.S.C. §112 ¶1 as set forth at pp. 3-12 ¶4-27 in the previous Office Action (15 March 2004) is *withdrawn* in view of Applicant's amendments (15 September 2004).
4. The Rejection of claim **25** under 35 U.S.C. §112 ¶2 as set forth at pp. 12 ¶28 in the previous Office Action (15 March 2004) is *withdrawn* in view of Applicant's amendments (15 September 2004).
5. The Rejection of claims **1, 16, 18, 19, and 21** under 35 U.S.C. §102(a) as set forth at pp. 12-13 ¶29-34 in the previous Office Action (15 March 2004) is *withdrawn* in view of Applicant's amendments (15 September 2004).
6. The Rejection of claims **1, 2, 6, 11, 12, 14, 17, and 20** under 35 U.S.C. §102(b) as set forth at pp. 14 ¶35-37 in the previous Office Action (15 March 2004) is *withdrawn* in view of Applicant's amendments (15 September 2004).

### ***New Objections And/Or Rejections***

***Claim Objections***

7. Claim **15** is objected to because of the following informalities: claim 15 depends from a rejected claim. Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

8. Claim **14** is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim does not provide units for the weight thus rendering the claim indefinite.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Claims **1, 4-6, 8-14, and 16-24** are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,573,916 (12 November 1996) Cheronis *et al.*
10. US '916 teaches an immunogenic construct comprising a carrier conjugated to a B-cell epitope and a helper T-cell epitope wherein the epitopes can be from the same species or different thus meeting the limitations of claims 1 and 20-23 (Col. 2-3, 6-7). US '916 teaches that

Art Unit: 1647

the B-cell and T-cell can elicit antigen-presenting cells thus meeting the limitations of claims 18-19 (Col. 4). US '916 teaches that the carrier may be naturally-occurring, semisynthetic, or synthetic and may be dextran (including those with a molecular weight of 500,000 Da), cellulose, agarose, and polyacrylamide thus meeting the limitations of claims 1, 4-6, and 8-14 (Col. 5-6). US '916 teaches that said immunogenic construct may contain epitopes (or "peptides" or "constructs") from bacteria, fungi, viruses, drugs, and chemicals thus meeting the limitations of claims 16 and 17 (Col. 3). US '916 teaches that said immunogenic construct can be included in a pharmaceutical composition comprising a carrier (vehicle), water (a diluent), or an adjuvant thus meeting the limitations of claim 24 (Col. 5).

11. Claims 1, 4, 5, 6, 8, 9, 10, 13, and 16-25 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,709,995 (20 January 1998) Chisari & Cerny.

12. US '995 teaches an immunogenic composition comprising a CTL epitope and a Helper T cell epitope conjugated via the N-terminus to a carrier molecule including but not limited to an immunogenic lipid, propylene glycol, polyethylene glycol, and other peptides thus meeting the limitations of claims 1, 4, 5, 6, 8, 9, 10, 13, and 16-25 (Col. 6, 10, 16, 53-54).

13. US '995 teaches an immunogenic composition comprising the same above in addition to a pharmaceutically acceptable carrier, excipient, diluent, and/or an adjuvant. US '995 teaches that the pharmaceutically adjuvants include but are not limited to oil formulations, aluminum phosphate, aluminum hydroxide thus meeting the limitations of claims 24 and 25 (Col. 14-17).

Art Unit: 1647

14. Claims 1, 4, 5, 6, 8, 9, 10, 11, 13, and 16-25 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,780,036 (14 July 1998) Chisari.

15. US '036 teaches an immunogenic composition comprising a CTL epitope and a Helper T cell epitope conjugated via the N-terminus to a carrier molecule including but not limited to an immunogenic lipid, cellulose, and other peptides thus meeting the limitations of claims 1, 4, 5, 6, 8, 9, 10, 11, 13, and 16-25 (Col. 2-3, 5-6, 10-11, 14).

16. US '036 teaches an immunogenic composition comprising the same above in addition to a pharmaceutically acceptable carrier, excipient, diluent, and/or an adjuvant. US '036 teaches that the pharmaceutically adjuvants include but are not limited to aluminum hydroxide thus meeting the limitations of claims 24 and 25 (Col. 3, 13-15).

### *Summary*

17. No claims are allowed.

Art Unit: 1647

***Conclusion***

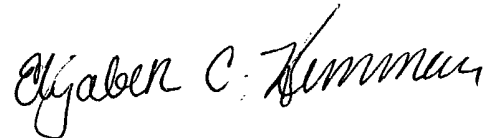
Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Christopher James Nichols, Ph.D.** whose telephone number is **(571) 272-0889**. The examiner can normally be reached on Monday through Friday, 8:00 AM to 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Brenda Brumback** can be reached on **(571) 272-0961**.

The fax number for the organization where this application or proceeding is assigned is **703-872-9306**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

CJN

November 23, 2004



ELIZABETH KEMMERER  
PRIMARY EXAMINER